

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
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SUBJECT: Region 3 Superfund Data Validation
Policy¹

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TO: Superfund Program Staff

Purpose:

The Environmental Protection Agency makes consequential decisions regarding public health and environmental conditions. Analytical data are the cornerstone of this Agency's decision making processes. Thus, it is imperative that the data used in these processes be of known and documented quality. The quality of analytical data is determined through the data validation process. Specifically, data validation is a systematic procedure for reviewing analytical data against a set of established criteria to determine its validity relative to the data's intended use. The purpose of this memo is to clearly define this Region's data validation policy for the Superfund program.

Background:

Each environmental data collection activity is different due to elements of variability which include site history, project objectives, and the amount of historical data available. The Site-specific procedures for data validation are specified in the individual Sampling and Analysis Plans developed for each site. Organizations performing environmental data collection activities should specify data validation requirements. These requirements should adequately support the intended use of the data.

Implementation:

Data review/validation procedures for this Region are delineated in:

Region III Modifications to the National Functional Guidelines for Data Review

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These procedures provide the reader with instructions on how to perform a full data validation.

EPA Region III advocates full data review/data validation to support quantitative Superfund Baseline Risk Assessments. This data validation is performed by an independent party other than the laboratory that generates the analytical data. The validation is performed on all (100%) of the data. **The appropriate qualifiers should be applied to 100% of the data.**

There are various EPA national guidance documents that address the objectives for data review/validation. Risk Assessment Guidance for Superfund, Volume 1 and the Guidance for Data Usability in Risk Assessment include discussions of data quality as a function of data use. For quantitative risk assessment, EPA National Guidelines indicate a preference for full data review.

For uses of data other than quantitative baseline risk assessment, the degree or intensity of data validation may vary based upon the intended use of the data. Region III's "Innovative Approaches to Data Validation" supports this concept.

The Region's primary goal is to verify that the data quality produced is adequate for the intended data use. The "Innovative Approaches to Data Validation" defines levels of data review which are based on how data are to be used. Each review level contains data validation evaluation criteria which support the data use category. However, it is important to note that under all circumstances the following conditions should be met

- The analytical deliverable requirement must contain all of the documentation listed in Appendix A of this memorandum.
- Data qualifiers are applied to 100 % of the data in all cases.
- **All data used to support quantitative baseline risk assessment should be reviewed using full Region III data validation procedures.**

The Region encourages dialogue between EPA and PRPs during the scoping phase of a project to establish site-specific data quality objectives that will meet the needs of each data collection activity. It should be emphasized that the scoping phase of the remedial process is the best time to present and discuss the data validation objectives of the project. An early and comprehensive discussion of the data validation procedures of the project will reduce the uncertainty during risk assessment. The final decision regarding the appropriate level of review must be approved by the EPA project manager.

Summary:

- Site specific data validation objectives are specified in the sampling and analysis plan each site.

Region III advocates 100% data validation to support any quantitative baseline risk assessment developed for the Superfund program.

For data uses other than quantitative baseline risk assessment, Region III Innovative Approaches may be used with EPA project manager approval.

Data Validation procedures are provided in the Regional Guidelines as noted above.